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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,548	10/14/2003	Jeffrey S. Bauer	6122-66637	3478

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,548	BAUER ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/4/03, 10/14/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 7, line 21 "FIGS. 1C-4F" should be --FIGS 1C-1F--..

Also the preliminary amendment filed October 14, 2003 correctly indicated that the application is a continuation of U.S. Patent Application No. 09/835,304 filed April 14, 2001, however, the preliminary amendment failed to indicate that U.S Patent Application No. 09/835,304 is now Patent No. 6,699,722.

The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear where the mobilization zone is located. Applicant recites that the sample application area, primary capture area and secondary capture area are in fluid continuous contact. There is no recitation indicating where the mobilization zone is located and therefore it is unclear what relationship exists between the mobilization zone and the sample application zone, primary capture area and secondary capture area. See also deficiency found in claim 22.

Claim 2, line 2, the recitation "associated with" is vague and indefinite. It is unclear how the detectable tracer molecule is associated with the device. Does applicant intend that the tracer molecule is bound to the device or does applicant intend something else?

Claim 6 is vague and indefinite because it contradicts independent claim 1. Claim 1 recites the device comprises a mobilization zone comprising a mobile or mobilizable detectable tracer molecule. Claim 6 recites the tracer molecule is placed on the device after a sample is placed on the device. It is unclear how the tracer is applied no earlier than the sample if the device already comprises the tracer before sample is applied.

Claim 6 is vague and indefinite because it is unclear if the tracer molecule is part of the device or not. If the tracer molecule is placed on the device after a sample then the tracer molecule was not part of the device before the operation of the device.

Claim 8 the recitation "the filter pad" there is insufficient antecedent basis for this limitation. Claim 8 should depend from claim 7.

Claim 9 the recitation "the at least one reagent" there is insufficient antecedent basis for this limitation. Claim 9 should depend from claim 8 and not claim 6.

Claim 11 the recitation "the first and second binding agents" there is insufficient antecedent basis for this limitation.

Claim 12 the recitation "the first and second binding agents" there is insufficient antecedent basis for this limitation.

Claims 15-19 are vague and indefinite because the analyte is not a positive limitation of the device.

Claim 16 is vague and indefinite because of the use of acronyms: i.e. HIV and HTLV. Although the terms may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The terms should be defined in their first instance.

Claim 20 the recitation "the second specific binding partner" there is insufficient antecedent basis for this limitation.

Claim 20 the recitation "the secondary capture area is such that the quantity of tracer molecule binding to the secondary capture area, and by correlation the amount of the analyte in a tested sample" is vague and confusing. It is unclear what applicant intends. Please clarify.

Claim 21 the recitation "the secondary specific binding partner immobilized" there is insufficient antecedent basis for this limitation.

Claim 21 the recitation "the chromatographic medium" there is insufficient antecedent basis for this limitation.

Claim 23 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble recites a method for detecting and/or quantitating an analyte but the body of the claim only recites the presence of the analyte.

Claim 23 the recitation "high affinity" is vague and indefinite. It is unclear what is considered to be high affinity.

Claim 29 the recitation "the first and second binding partner" there is insufficient antecedent basis for this limitation.

Claim 31 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim recites a method for detecting and/or quantitating an analyte but the body of the claim does not recite method steps for detecting and/or quantitating the analyte.

Claim 33 the recitation "the mobile detectable analyte analog" there is insufficient antecedent basis for this limitation.

Claim 33 is vague and indefinite because it contradicts independent claim 1. Claim 1 recites the device comprises a mobilization zone comprising a mobile or mobilizable detectable tracer molecule. Claim 33 recites wherein the mobile detectable analyte analog is applied to the device no earlier than the sample is applied to the device. It is unclear how the detectable tracer is applied no earlier than the sample if the test strip already comprises the tracer before sample is applied.

Claim 34 the recitation "the analyte-tracer conjugate" there is insufficient antecedent basis for this limitation.

Claim 34 is vague and indefinite because it contradicts independent claim 1. Claim 1 recites that the device comprises a mobilization zone comprising a mobile or mobilizable detectable tracer. Claim 34 recites that the tracer is mixed with the sample prior to application of the sample to the sample application area. It is unclear how the tracer is mixed with the sample prior to application of the sample if the device already comprises the tracer before sample is applied.

Claim 36 the recitation "the test strip device" there is insufficient antecedent basis for this limitation.

Claim 42 is vague and indefinite because "sufficient" is a relative term which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 45 the recitation "the chromatographic assay device" there is insufficient antecedent basis for this limitation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 7, 8, 10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Luo et al (5,229,073).

Luo et al disclose a device for measuring levels of analyte in a sample. Luo et al disclose that the device comprises a sample loading area (sample application area); a application pad containing labeled reagents (a mobile or mobilizable detectable tracer molecule) and a plurality of capture sites (primary and secondary capture areas) having immobilized reagent which binds the analyte and the labeled analyte analog (col 5, lines 1-68 and Figures 1a and 1b). Luo et al disclose that the device can comprise a filter (col 6).

6. Claims 1, 10, 11, 13-15, 20, 23-25, 27, 31-34, 36, 39, 40, 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer et al (W0/98/39657).

Boehringer et al disclose a device and method for determining an analyte of interest. Boehringer et al disclose the device comprises a sample receiving zone (sample application area); a labeling zone (mobilization zone); and primary and secondary capture zone (Figure 1). Boehringer et al disclose that the labeling zone can comprise a labeled analyte analog. Boehringer et al disclose that the capture zones comprise an immobilized specific binding pair member. Boehringer et al disclose that the analyte and labeled analyte analog (tracer molecule) compete for binding to the immobilized binding pair member. Boehringer et al also disclose that the sample flows sequentially past the capture zones (p. 16, lines 9-38). Boehringer et al also disclose that the device and components can be packaged in the form of a kit and that the kit

can also contain instructions for performing the methods and interpreting the results (p. 36, lines 1-8).

7. Claims 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Mendel-Hartvig (WO 99/36/776).

Mendel-Hartvig et al. disclose a method of determining an analyte of interest. Mendel-Hartvig et al disclose applying a sample suspected of containing the analyte to a substrate comprising multiple detection zones (p. 13). Mendel-Hartvig et al disclose that the detection zones comprise an immobilized reagent which binds to the analyte and a labeled analyte (p. 10, line 33 – p. 11, line 12). Mendel-Hartvig et al disclose that the sample and reagents can be added simultaneously or sequentially.

Claim Rejections - 35 USC § 103

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 2, 7, 8, 10-15, 20-25, 28-32, 35, 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friesen et al (US 4,861,711) in view of Luo et al (US 5,229,073).

Friesen et al disclose a test strip and methods for the determination of substances of biological affinity in biological fluids. Friesen et al disclose that the test strip has a reagent zone (mobilization zone) comprising mobilized labeled analyte (detectable tracer). Friesen et al disclose that the test strip has a sample application zone, which can be located at different places (col 2, lines 50-53, Figures 1 and 2). Friesen et al disclose that the strip comprises a detection zone (primary capture zone). Friesen discloses that the strip can comprise several solid phase zones, which are appropriate for an analyte and different measurement ranges of this analyte (col 2, lines 21-25). Friesen et al disclose that the test strip can comprise a filter for eliminating interfering factors (col 2, lines 54-68) and that the filter can comprise components (reagents) to eliminate the interfering substances. Friesen et al disclose that the sample containing the analyte renders mobile a predetermined amount of labeled analyte contained in the diagnostic agent (col 5, lines 45-55) and that the detection zone comprises an immobilized binding partner which binds has an affinity for the analyte and also has an affinity for the labeled analyte.

Friesen et al fails to specifically teach that a secondary capture area immobilized binding partner having a binding affinity for the analyte and a binding affinity for the detectable tracer.

Luo et al disclose a test strip and method for determining levels of an analyte of interest. Luo et al disclose that the test strip contains a plurality of individual capture sites containing immobilized anti-antibody to which the analyte and labeled antigen competitively bind (col 2, lines 43-54). Luo et al disclose that the use of these capture sites provides the benefit of a rapid one-step, non-instrumented competitive immunochromatographic method (col 2, lines 9-15).

It would have been obvious to one of ordinary skill in the art to incorporate secondary capture zone with immobilized reagents as taught by Luo et al into the method of Friesen et al because Luo et al shows that the use of these capture sites provides the benefit of a rapid one-step, non-instrumented competitive immunochromatographic method.

With respect to the recitation that the tracer migrates with the liquid sample, but reaches the primary capture zone after the analyte in the liquid sample as recited in the instant claims. Since it is unclear where the mobilization zone is located in the path of liquid flow and since Friesen et al disclose that the sample can be located downstream of the reagent zone (mobilization zone) (Fig. 2). One of ordinary skill in the art will recognize that when the sample is applied it would also flow toward the detection zone and toward the mobile phase (as shown in Fig. 2). And when the liquid in mobile phase

is introduced it would cause the flow of the mobilized reagent to flow toward the detection zone and thus would reach the detection zone after the analyte.

11. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al (WO/98/39657).

See above for teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically state that the detectable tracer molecule migrates through the device at a rate slower than a rate at which the analyte in a sample migrates through the device and that the slower migration of the tracer molecule is caused by a molecular weight of the tracer molecule.

Although Boehringer et al does not specifically state the slower rate as recited in the claims, Boehringer et al does disclose that the detectable tracer molecule can be a labeled analyte analog (p. 9). Boehringer et al disclose that the analyte analog refers to a modified analyte in which the analyte has been modified to provide a means for attaching the analyte to another molecule. Boehringer et al disclose attaching this analyte analog to BSA coated latex microspheres (p. 43-45). Since the microspheres of Boehringer et al are even larger (0.51u) than the particles disclosed in the specification on page 21 and are coated with BSA, one of ordinary skill in the art would recognize that the rate of migration for the labeled analyte analog would be slower than the rate of migration of the analyte.

12. Claims 3, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friesen et al in view of Luo et al as applied to claims 1, 2, 7, 8, 10-15, 20-25, 28-32, 35, 36 and 39 above, and further in view of Davis et al (US 6,352,862).

See above for teachings of Friesen et al in view of Luo et al.

Friesen et al and Luo et al differ from the instant invention in failing to teach the detectable tracer is a tracer that migrates through the test strip at a rate slower than a rate at which the analyte in the liquid sample migrates through the test strip.

Davis et al disclose the use of particulate labels (detectable tracer) such as latex particles or gold sols. Davis et al disclose that these particulate labels range in size from 0.05 to about 0.5 microns (50 to 500 nm). Davis et al disclose that these labels can be used to produce an instant analytical result without the need to add further reagents in order to develop a detectable signal. They are robust and stable and can therefor be used readily in a analytical device, which is stored in the dry state (col 2, lines 50 – col 3 line 6).

It would have been obvious to one of ordinary skill in the art to incorporate particulate labels such as taught by Davis et al into the modified test strip and method of Friesen et al because Davis et al shows that these labels can be used to produce an instant analytical result without the need to add further reagents in order to develop a detectable signal. They are robust and stable and can therefor be used readily in an analytical device which is stored in the dry stat.

With respect to the rate of migration as recited in the instant claims. Since the particulate labels of Davis et al have the same size as the labels disclosed by the applicant (Specification, p. 21, lines 6-13). One of ordinary skill in the art would recognize that the rate of migration for the particulate labeled analyte would be slower than the rate of migration of the analyte.

13. Claims 9 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friesen et al in view of Luo et al as applied to claims 1, 2, 7, 8, 10-15, 20-25, 28-32, 35, 36 and 39 above, and further in view of Thieme et al (US 5,871,905).

See above for teachings of Friesen et al and Luo et al.

Friesen et al and Luo et al differ from the instant invention in failing to teach the liquid sample is saliva and that the saliva is combined with a bile acid or bile salt.

Thieme et al disclose the use of saliva as a liquid sample in immunoassays involving lateral flow immunochromatographic devices (col 1). Thieme et al disclose that the saliva is combined with a bile salt or acid (col 3, lines 19-25). Thieme et al disclose that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample. Thieme et al also disclose that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives (col 15, lines 42-61).

It would have been obvious to one of ordinary skill in the art to use saliva as a liquid sample because it is well known in the art that saliva can be used as a sample (Thieme et al, see also Fitzpatrick et al US 5,451,054, col 1, lines 19-20). It would also have been obvious to one of ordinary skill in the art to incorporate a bile acid or bile salt in combination with the saliva as taught by Thieme et al into the modified method of Friesen et al because Thieme et al shows that the saliva sample combined with the bile

acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample.

It would have also been obvious to one of ordinary skill in the art to incorporate a chelator such as taught by Thieme et al into the modified test strip and method of Friesen et al because Thieme et al shows that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives.

14. Claims 16-19, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friesen et al in view of Luo et al as applied to claims 1, 2, 7, 8, 10-15, 20-25, 28-32, 35, 36 and 39 above, and further in view of Fitzpatrick et al (US 5,451,504).

See above for teachings of Friesen et al and Luo et al.

Friesen et al and Luo et al differ from the instant invention in failing to specifically teach the analytes.

Fitzpatrick et al disclose test strips, which will detect any antigen in which the appropriate reagents are used. Fitzpartrick et al disclose that the analyte can be drugs and small analytes of 100 to 1000 Daltons (col 4). Fitzpartrick et al disclose that detecting drugs or drug metabolites affects the choice of proper medical treatment and that the detection of drugs or drug metabolites in a person is also important in law enforcement.

It would have been obvious to one of ordinary skill in the art to detect any analyte and incorporate the appropriate reagent such as taught by Fitzpatrick into the modified test strip and method of Friesen et al because Fitzpatrick et al shows that the detection of analytes affects the choice of proper medical treatment.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 18-20 and 25-37 of U.S. Patent No. 6,699,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the claims or U.S. Patent No. 6,699,722 would encompass the claims of 1-38 of application 10/686,548.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
November 4, 2004

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11/12/04